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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte YI FENG ZHENG, HSHIOU-TING LIU
and YALI YANG

Appeal 2010-001050
Application 10/736,004
Technology Center 1600

Decided: June 15, 2010

Before ERIC GRIMES, DEMETRA J. MILLS, and
MELANIE L. McCOLLUM *Administrative Patent Judges.*

MILLS, *Administrative Patent Judge.*

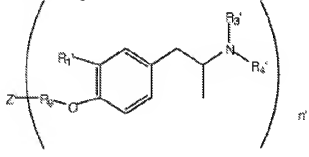
DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for obviousness. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF CASE

The following claim is representative.

25. A method for determining methylenedioxyamphetamine and/or methylenedioxymethamphetamine and/or methylenedioxyethamphetamine in a sample suspected of containing methylenedioxyamphetamine and/or methylenedioxymethamphetamine and/or methylenedioxyethamphetamine, said method comprising:
(a) providing in combination in a medium:
(i) said sample,
(ii) an antibody for methylenedioxyamphetamine, and/or
(iii) an antibody for methylenedioxymethamphetamine, and/or
(iv) an antibody for methylenedioxyethamphetamine, and
(v) a compound of the formula:



wherein:

$R^{1'}$ is H, or methyl or ethyl
$R^{3'}$ is H,
$R^{4'}$ is H, or methyl or ethyl,
R^{9} is $-(CH_2)_nC(O)$,
Z' is an enzyme,
n is an integer from 1 to 5,
n' is an integer between 1 and the molecular weight of said enzyme divided by about 500;
and
(b) examining said medium for the presence of a complex comprising said methylenedioxyamphetamine and said antibody for methylenedioxyamphetamine and/or a complex of said methylenedioxymethamphetamine and said antibody for

methylenedioxymethamphetamine and/or a complex of said methylenedioxyethamphetamine and said antibody for methylenedioxyethamphetamine, the presence thereof indicating the presence of said methylenedioxyamphetamine and/or methylenedioxymethamphetamine and/or methylenedioxyethamphetamine in said sample.

Additional Appealed claims may be found in the Claims Appendix to the Brief.

The Examiner relies on the following evidence:

Avenia et al.	US 4,041,076	Aug. 9, 1977
Rouhani et al.	GB 2361473 A	Oct. 24, 2001
Hui	EP 1340981 A2	Feb. 25, 2003

Grounds of Rejection

1. Claims 25, 27, 30 and 31 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hui, in view of Avenia.

2. Claims 25, 27, 30 and 31 are rejected under 35 U.S.C. §103(a) as being unpatentable over Rouhani in view of Avenia.

PRINICIPLES OF LAW

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007).

Discussion

Claims 25, 27, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hui in view of Avenia. (Ans. 3.)

ISSUE

The Examiner finds that "it would have been obvious at the time of the invention to a person of ordinary skill in the art to substitute equivalent hapten, immunogen or antibody as disclosed by Avenia *et al* in the method of Hui *et al*, with the expectation of obtaining a similarly useful immunoassay method and kit for detection of amphetamine and amphetamine derivatives." (*Id.* at 4.)

Appellants contend that, "[t]he combined teaching[s] of Hui and Avenia is deficient in not disclosing or suggesting at least the following limitation of claim 25: "providing in combination in a medium, together with the sample and the antibodies, an enzyme label conjugate of the formula set forth in the claim having a $-(CH_2)_nC(O)$ moiety linking the enzyme to the molecule." (App. Br. 8-9.)

The issue is: Do the cited references disclose or suggest the limitation of claim 25: "providing in combination in a medium, together with the sample and the antibodies, an enzyme label conjugate of the formula set forth in the claim having a $-(CH_2)_nC(O)$ moiety linking the enzyme to the molecule." (*Id.*)

FINDINGS OF FACT

1. "Hui… disclose[s] various competitive and noncompetitive methods/assays and a kit for detection and quantitative determination of

amphetamine derivatives such as MDA, MDMA, MDEA, MDPA, BDB, MBDB etc (paragraphs [0012], [0024], [0029], [0064-0067], [0059] and [0060]) using antibody against amphetamine derivatives and label derivatives (such as fluorescent, luminescent, radioactive isotope etc.) (paragraph [0022])." (Ans. 3.)

2. "Hui's amphetamine derivatives and immunogens are similar to the compound and immunogen of the present invention and are expected to recognize different amphetamine derivatives suitable for different immunoassays. However, the linking group or the position of linker at the amphetamine derivative is different from the present compound." (*Id.* at 3-4.)

3. Hui discloses the creation of antibodies for detecting specific amphetamine derivatives and their use in assays including competitive assays. (Hui, ¶¶ 0066-0067.)

4. Hui describes an activated hapten which is a compound such as an amphetamine derivative linked via a linking group or linker to a label which may be an enzyme. (Hui, ¶¶ 0014-0022.) The linking group may or may not be needed. (Hui, ¶ 0019.)

5. Avenia discloses a radioimmunoassay for amphetamine derivatives which uses an amphetamine derivative having the linking group recited in claim 25 to form haptens and raise antibodies (Avenia, col. 4, l. 59 to col. 5, l. 10; abstract.)

6. "Avenia *et al*[.] disclose[s] amphetamine immunogen, labeled tracer and antibodies … and disclose competitive immunoassay method for detection of phenentylamines [sic, phenethylamines] (e.g. norepinephrine,

dopamine, epinephrine and amphetamines)." (Ans. 4.) Labeled phenethylamines may be enzyme labeled. (Avenia, col. 4, ll. 47-59.)

7. The Examiner finds that "[t]he immunogen of Avenia et al. is the same as the immunogen of present application." (Ans. 4.)

8. The Examiner concludes that "[s]ince detection of amphetamine, methamphetamine and their derivatives is important in the field of ecstasy drug and once a hapten, immunogen or an antibody is available, one of ordinary skill in the art would obviously try to use the hapten and the immunogen in different immunoassay methods to develop a better detection assay for the drug." (*Id.*)

9. The Examiner concludes that "given the above fact, it would have been obvious at the time of the invention to a person of ordinary skill in the art to substitute equivalent hapten, immunogen or antibody as disclosed by Avenia *et al* in the method of Hui *et al*, with the expectation of obtaining a similarly useful immunoassay method and kit for detection of amphetamine and amphetamine derivatives." (*Id.*)

10. "Claims recite methods, compositions and kits for detecting the presence and/or amounts of entactogens in samples." (*Id.* at 5.)

11. "Rouhani *et al* disclose[s] a method for detection of ecstasy-class analogs." (*Id.*)

12. "Rouhani discloses preparation of antibody (page 6, lines 19-24; pages 16-18) using the compound conjugated with carrier protein (see abstract) and different homogeneous and heterogeneous immunoassay methods (pages 8-9 and 34) and assay kit (page 31, lines 9-12 and claim 10) for detection and quantitation of ecstasy-class analogs in biological samples (page 22, lines 19-24)." (*Id.* at 5.)

13. "Rouhani also discloses the … compound conjugated with a protein to be adapted as immunogen (page 41, example 7). Attachment to a carrier protein or a label is also inherent in the process of immunization (see claims 7 and 8) and immunoassay methods (see pages 8-9 and 34) as disclosed in this reference." (*Id.*)

14. "Rouhani's amphetamine and methamphetamine derivatives and immunogens are similar to the compound and immunogen of the present invention and are expected to recognize different amphetamine derivatives suitable for different immunoassays." (*Id.*) Rouhani discloses an immunoassay for ecstasy amphetamine derivatives that employs an enzyme that undergoes change in activity. (Rouhani, 7.)

15. "However, the linking group or the position of linker at the amphetamine derivative is different from the present compound." (Ans. 5.)

16. "Avenia *et al* disclose[s] amphetamine immunogen, labeled tracer and antibodies … and disclose [a] competitive immunoassay method for detection of phenentylamines [sic, phenethylamines] (e.g. norepinephrine, dopamine, epinephrine and amphetamines)." (*Id.*) The Examiner concludes that the immunogen of Avenia *et al* is the same as the immunogen of present application. (*Id.*)

ANALYSIS

The Examiner finds that "it would have been obvious at the time of the invention to a person of ordinary skill in the art to substitute equivalent hapten, immunogen or antibody as disclosed by Avenia *et al* in the method of Hui *et al*, with the expectation of obtaining a similarly useful

immunoassay method and kit for detection of amphetamine and amphetamine derivatives." (*Id.* at 4.)

Appellants contend that, "[t]he combined teaching[s] of Hui and Avenia is deficient in not disclosing or suggesting at least the following limitation of claim 25: 'providing in combination in a medium, together with the sample and the antibodies, an enzyme label conjugate of the formula set forth in the claim having a $-(CH_2)_nC(O)$ moiety linking the enzyme to the molecule.'" (App. Br. 8-9.) More particularly, Appellants argue that there is no mention in Avenia of a conjugate of a label and the haptens of Avenia where the label is linking through the claimed linking moiety. (App. Br. 10.) Appellants argue there is no disclosure in Avenia of linking a phenethylamine to a label by means of the claimed linking moiety. (App. Br. 10.)

We conclude that the Examiner has the better argument. In the present case, the Examiner finds that Hui discloses the creation of antibodies for detecting specific amphetamine derivatives and their use in assays including competitive assays. (Hui, ¶¶ 0066-0067.) Hui describes an activated hapten which is a compound such as an amphetamine derivative linked via a linking group or linker to a label which may be an enzyme. (Hui, ¶¶ 0014-0022.) The linking group may or may not be needed. (Hui, ¶ 0019.) Hui does not disclose the claimed linker, so the Examiner relies on Avenia which discloses a radioimmunoassay for amphetamine derivatives which uses an amphetamine derivative having the claimed linking group to form haptens and raise antibodies (Avenia, col. 4, l. 59 to col. 5, l. 10; abstract.) It would have been obvious to one of ordinary skill in the art to attach an enzyme label to the hapten of formula III of Avenia via the linker

of Avenia and substitute the labeled hapten for the hapten of Hui and use it in a competitive assay, as claimed.

Appellants further argue that the labeled radioisotope of Avenia does not include the claimed linker, as the linker is used only as part of a hapten or immunogen to create antibodies for the Avenia radioimmunoassay. (App. Br. 11.) Finally, Appellants argue that radiolabelled phenethylamine with no linking group performed better in a radioimmunoassay and therefore the prior art teaches away from use of enzyme labeled amphetamine derivatives attached via a linker in a competitive assay. (App. Br. 11.)

Appellants have provided no evidence that one of ordinary skill in the art would not have been able to substitute the hapten of Avenia formula III in the assay of Hui to detect amphetamine derivatives. Thus it would have been obvious to substitute a homologous methamphetamine hapten or immunogen having the claimed linker, for a known labelled amphetamine in a known competitive assay. An "[e]xpress suggestion to substitute one equivalent for another need not be present to render such substitution obvious." *In re Fout*, 675 F.2d 297, 301 (CCPA 1982). It is known to use the claimed linking moiety as described in Avenia. The combination of familiar elements (the linking moiety of Avenia in a methamphetamine assay as in Hui) according to known methods is likely to be obvious when it does no more than yield predictable results. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007).

We do not find that the prior teaches away from the combination of the cited references. "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction

divergent from the path that was taken by the applicant. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). We find no suggestion in Avenia or Hui of an unproductive result from the indicated combination and thus find no clear teaching away from the combination as alleged by Appellants. "The fact that the motivating benefit comes at the expense of another benefit, such as superior assay results, should not nullify its use as a basis to modify the disclosure of one reference with the teachings of another. Instead, the benefits, both lost and gained, should be weighed against one another." *Medichem S.A. v. Rolabo S.L.,* 437 F.3d 1157, 1165 (Fed. Cir. 2006).

The obviousness rejection of claim 25 is affirmed. Appellants present similar argument in the Brief for claims 27, 30 and 31, and the rejection of these claims is affirmed based on the reasoning for claim 25 herein.

CONCLUSION OF LAW

The combined teachings of Hui and Avenia disclose the limitation of the claims: "providing in combination in a medium, together with the sample and the antibodies, an enzyme label conjugate of the formula set forth in the claim having a $-(CH_2)_nC(O)$ moiety linking the enzyme to the molecule."

2. Claims 25, 27, 30 and 31 are rejected under 35 U.S.C. §103(a) as being unpatentable over Rouhani in view of Avenia.

Appellants present the same arguments for the rejection of Rouhani in view of Avenia as presented for the rejection of Hui in view of Avenia. (App. Br. 24.) Similar to Hui, Rouhani discloses an immunoassay for ecstasy amphetamine derivatives that employs an enzyme that undergoes change in activity. (Rouhani, 7.) Rouhani discloses immunogens which generate antibodies that recognize different amphetamine derivatives. (Page 41, Example 7.) Avenia discloses the same immunogen and hapten, and the same linking group, as claimed which can be substituted by one of ordinary skill in the art for the immunogen of Rouhani.

Thus, employing the same analysis for the combination of Rouhani and Avenia as for Hui and Avenia, we affirm the obviousness rejection.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

alw

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